Remarks

The Examiner has provided two rejections that are addressed in the following order:

I. Claims 1 and 3-5 are rejected under 35 USC § 112 ¶ 2 as allegedly being indefinite.

II. Claims 1 and 3-5 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 5,066,491 to Tokoro et al., in view of United States Patent No. 5,080,895 to Stott et al.

I. The Claims Are Not Indefinite

The Examiner has reasserted this rejection because:

> Applicants' argument[s] filed 2/27/06 ... are not persuasive. ... the claims must include enough information to clearly and accurately describe the invention.

Office Action pg 2 ¶ 4. The Applicants believe the previous response was persuasive and is herein incorporated by reference in addition to these additional arguments.

In the previous Office Action the Examiner stated that:

> The term "method" recited in claims 1 and 3-5 is ambiguous and unclear and the metes and bounds of the claimed "method" is not defined.

Office Action Mailed 09/20/05 pg 2 ¶ 5. Further, the Examiner points out that "... claim 1 is not drafted to recite treatment as well as prevention". *Office Action pg 2 ¶ 4.* The Applicants believe that the broad nature of Claim 1 does, in fact, encompass both therapeutic treatments as well as prophylactic treatments.[1] Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have

[1] Both embodiments are disclosed in the Applicants' Specification. See pg 5 ln 21 – pg 6 ln 6.

amended Claim 1 to recite a method for "administering an antibody reactive with *Clostridium perfringens*". New Claims 6 & 7 are then added to further clarify that the method may be "prophylatic" or "therapeutic" in nature. The Applicants believe that the Examiner should now see that Claim 1 includes prophylactic and therapeutic administration. But now these specific embodiments are explicitly defined in dependent claims and must be considered in the proper interpretation of Claim 1 under the Doctrine Of Claim Differentiation:

> ... we must not interpret an independent claim in a way that is inconsistent with a claim which depends from it ...

Wright Medical Technology, Inc. v. Osteonics Corp. 122 F.3d 1440, 1445, 43 USPQ2d 1837, 1841 (Fed. Cir. 1997). These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants, therefore, respectfully request that the Examiner withdraw the rejection.

II. The Claims Are Not *Prima Facie* Obvious

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A Prima Facie Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criteria. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

A. Tokoro et al. and Stott et al. Do Not Provide Any Motivation To Combine Their Teachings

The Examiner has made a conclusion regarding the proposed combination of teachings within Tokoro et al. and Stott et al. that is not relevant to the Applicants' claimed invention. Specifically, the Examiner stands on the statement that:

> Therefore, the combination of teachings to yield mass production of inexpensive antibodies remains obvious.

Office Action pg 3 ¶ 6. The Examiner appears to be arguing that by combining the references, one achieves mass production of inexpensive antibodies. As shown below, the Examiner's argument is specious. A careful reading of Sott et al. reveals that achievement of mass production of inexpensive antibodies without immunization. To combine Stott et al. with Tokoro et al. is to force Stott et al. to take a step backwards.

1. Stott et al. Teaches Away From Tokoro et al.

Stott et al. contains no suggestions to motivate one having ordinary skill in the art to seek and try methods of producing an immunologically active solution, other than the disclosed method for the extraction and purification of whey. In particular, Stott et al. provides no teaching that any immunization methods should, or could, be considered. Much less suggesting that avian antibodies be collected from egg yolks following hen immunization.[2] Consequently, there is no motivation for one having ordinary skill in the art to combine the teachings of Stott et al. with the teachings of Tokoro et al.

Stott et al. summarizes their invention clearly:

> The present invention relates to a process for extracting and concentrating the Ig molecules found in whey ...

Stott et al. col 5 ln 19-21 [emphasis added]. There is no place in Stott et al. where the step of immunizing is added to the above process. Further, Stott et al. clearly establishes that the proposed method is feasible:

[2] Stott et al. is limited to the isolation of naturally produced immunoglobulin mixtures from the milk of unimmunized cows.

> Although approximately 85,000,000 metric tons of whey is created annually as a byproduct of cheese production worldwide, about 34,000,000 metric tons of whey cannot be economically utilized. The whey byproduct useful in practicing the present invention can therefore be obtained at minimal cost and will reduce the burden of disposing the unwanted whey.

Stott et al. col 5 ln 36-43. With an almost unlimited amount of source material, that is basically one man's garbage, who needs immunization?

Specifically, Stott is directed towards the mass production of naturally produced antibodies to protect newborn cows because colostrum provides insufficient protection:

> Consumption of an insufficient quantity of colostrum or consumption of a low Ig concentration colostrum produces a deficient level of passive immunity transfer. If a calf having this deficient level of passive immunity is exposed to a disease, there is a high probability that it will contract the disease, require expensive medical treatment and may die or lack sufficient growth potential.

Stott et al., col 2 ln 42-49. Stott et al., therefore, posed the problem of immunologically protecting a large number of animals. *Stott et al. concluded that immunization (as is taught by Tokoro et al.) was* ***not*** *the answer*:

> Another existing technique for enhancing the disease resistance of a calf to a specific disease involves prepartum vaccination of the dam. The vaccination increases the serum blood level concentration of the desired pathogen specific antibody and ultimately yields colostrum having enhanced levels of the desired antibody. ... Although these laboratory testing activities have substantially increased the level of knowledge of the natural passive immunity transfer mechanism in animals, they have not solved the immunity transfer problems outlined above by providing a method for positively controlling the Ig concentration and distribution of pathogen specific antibodies in colostrum.

Stott et al. col 3 ln 25-48 [emphasis added]. Clearly, the teachings of Tokoro et al. have not been suggested as desirable within Stott et al. This situation cannot support an obviousness rejection:

> Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.

In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Stott et al. does not suggest the desirability of immunization and clearly rejects the very concept. To solve the problem posed by Stott et al. with Tokoro et al., every cow in the world would have to be individually injected with an immunizing agent, a ridiculous proposition.

A further question is, with what immunization agent? Tokoro et al. only teaches immunization against *E. coli* bacteria. Stott et al. does not properly describe or suggest the use of any specific immunization agents. The Examiner is requested to reevaluate the context of Stott's following paragraph where *Clostridium perfringens* is merely mentioned as one possible microbe to which cows may be exposed:

> Calves are commonly exposed to and require adequate passive immunity to the following pathogens:
>
> 1. Escherichia coli
> 2. Salmonella dublin
> 3. Clostridium perfringens, types B and C
> 4. Clostridium chauvei
> 5. Haemophilus somnus
> 6. Myxovirus parafluenza 3
> 7. Infectious Bovine Rhinotracheitis; and
> 8. Salmonella typhimurium ...

Stott et al. col 10 ln 38-61 [emphasis added]. This list only identifies commonly occurring bacteria to which a calf might, or might not be exposed, during early development. Stott et al. never suggests that immunizing agents be developed for any of these bacteria, including the *Clostridium* species.

2. Tokoro et al. Is Contrary To Stott's Teachings

Tokoro et al. does not provide any suggestions to motivate one having ordinary skill in the art to seek and try methods of producing an immunologically active solution, other than the disclosed method for immunizing hens and collecting antibodies from eggs.[3] The Examiner is reminded that:

[3] Tokoro et al. provides no suggestions that immunological factors should be isolated from the milk of unimmunized cows.

> The mere fact that the prior art could be modified in the manner proposed by the Examiner would not have made the modification obvious unless the prior art suggested the desirability of the modification.

Ex parte Dussard, 7 USPQ2d 1818, 1820 (Bd. Pat. App. & Int., 1988). In particular, Tokoro et al. provides no teaching that any antibody should, or could, be isolated from any dairy product. Much less suggesting that antibodies be collected from whey during the commercial production of cheese. Consequently, there is no motivation for one having ordinary skill in the art to combine the teachings of Tokoro et al. with the teachings of Stott et al.

The Applicants, therefore, respectfully request that the Examiner withdraw the present rejection.

CONCLUSION

Applicants believe that the arguments set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejections be withdrawn for the reasons set forth above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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